# **Way to Health Content and Messaging**

# Introduction and purpose

The IRB must review all content that participants will see throughout the course of a study being run on Way to Health (W2H). This document provides a framework for how to present this information.

Please keep in mind

* You should use this document as a guide to create your own patient-facing content.
* DO NOT submit this document as is to the IRB.
* You must include all the content that participants will see during the enrollment process – this is particularly important for projects utilizing the participant portal for enrollment and consent.
* You must also include all messaging for each arm of the intervention (e.g., welcome messages, daily feedback, survey reminders, etc.). Feel free to repurpose the copy you’ve already outlined in the W2H Arm Schedules protocol mapping in this section.

# **Patient-facing content template (populated with STEP UP study details)**

## **Enrollment for all arms**

#### 1. W2H welcome screen

Welcome! The STEP UP study team has partnered with Way to Health, a technology platform at the University of Pennsylvania to launch STEP UP, a 6-month research study to test ways to help individuals increase physical activity.

To participate, you must be willing to wear an activity tracker to monitor your daily step counts and have no medical conditions stopping you from participating in a 6-month physical activity program. You can begin by clicking “Enroll” at the bottom of the page. If you’ve already created an account, you can login using your username or email address with your password.

You will need about 25-30 minutes to complete the registration process. Here is a brief overview of the enrollment process:

1. Create & verify account

2. Complete profile

3. Informed consent

4. Determine eligibility

5. Complete a brief survey

6. Set up your device

7. Test your device

If you have any questions about the study, please email us at stepup@example.com or call us at XXX-XXX-XXXX.

2. Profile

To begin, click on “Enroll” and complete the sections below. Please be sure to enter an email address you check daily. If you do not have an email address, you can create one at www.gmail.com.

* Email address
* Email address (confirm)
* First name
* Last name
* Desired username
* Password
* Password (confirm)

3. Email confirmation

A confirmation has been sent to the email address you provided. Please check your email to verify your account and then log in to continue

#### 4. Profile

In the next step, we will ask you to provide some additional contact information. When you are ready, please click the continue button below.

After completing your profile information, please select whether you would like to primarily receive study communications by text message, email, or interactive voice recording. Please be aware that standard text messaging and phone call charges may apply based on your phone plan. Please select a method that you will be able to check daily and note that you can log in to the study site to change these preferences at any time.

* DOB
* Home phone
* Cell phone
* Alert preferences: email, text message, phone call

Thank you for completing your profile. Please return to the main menu by clicking the "Back to Roadmap" button below.

#### 5. Informed consent – note that Informed consent will be uploaded separately and that the potential participant will be stepped through the consent, page by page.

Next, we will let you review information about the study. The study is voluntary, and you will be asked to provide your informed consent if you would like to participate. To read through the consent form, click the “complete” button below.

* Yes, I want to participate
* No, I do not want to participate: if this is selected: Please tell us why you chose not to participate: a) I am not interested; b) I do not understand the study; c) I am concerned about the risks of the study; d) I do not want to use Way to Health or the devices necessary to participate in the study; e) I am not ready to participate in a physical activity program.

If consented: Thank you for completing the Informed Consent for the STEP UP Study!

If declined: Thank you for your interest. Study staff is available if you have any concerns about the study. You may reach us at STEP UP.

6. Screening survey

Next, we will ask you a few questions to ensure this study is a good fit for you.

* Screening/eligibility survey
* If not eligible: Thank you for your interest in this study. However, based on your responses, it does not seem that this study is the right fit for you. If you have any questions or would like to discuss your eligibility, please email us at stepup@example.com or call us at XXX-XXX-XXXX.

If eligible: Thank you for completing the screening survey. So far it appears that this study may be a good fit for you. Please return to the main menu to complete the participation preference survey.

#### 7. Eligibility confirmation

The following message will appear on the participant’s enrollment dashboard while we wait for everyone to finish enrolling and for randomization to take place:

“Study staff is confirming your eligibility and will get back to you within 1-2 weeks. If you have any questions, please feel free to contact us at stepup@example.com. Thank you for your patience!”

#### 8. Device setup

If a participant needs to obtain a Fitbit Flex, provide information on how to contact the study team to obtain the device and then return to Way to Health to set up their Fitbit account and allow Way to Health to access Fitbit data.

9. Baseline period

Congratulations on setting up and connecting your device to Way to Health. Now, you have a few weeks to get accustomed to using the device to track your steps. Remember to try you’re your Fitbit anytime you move or exercise. After a few weeks, you’ll receive a message from the study to log back into Way to Health for further instructions. If you have any questions or issues with your device, please email us at stepup@example.com.

10. Goal setting

Welcome back. We hope you have had a chance to get accustomed to using your device to track your steps.

In this study, we’d like to help you increase your level of physical activity. Higher levels of physical activity are associated with improved overall health, weight loss, and lower risks of cardiovascular disease. Based on prior evidence, 7000 steps per day is the minimum level of activity to start achieving these health benefits. However, higher levels of activity such as 10,000 steps might bring more benefits.

We’d like you to select one of the following daily step goals above your baseline.

* 6000 steps per day
* 8000 steps per day
* 10000 steps per day
* Or set your own goal: \_\_\_\_\_\_ steps per day

## **Intervention**

#### Control arm

1. Daily feedback when achieved goal: Great job! You had XXXX steps yesterday and achieved your goal of at least YYYY steps per day. Keep it up!
2. Daily feedback when not achieving goal: Sorry, you had XXXX steps yesterday and did not achieve your goal of at least YYYY steps. Try to stay physically active and meet your goal each day!

#### Gamification arm

The study will begin on Monday. Please remember to carry your device with you any time you move, are physically active, or exercise. At approximately 10 am each day, you’ll receive performance feedback on whether you achieved your goal on the prior day.

The study will last 24 weeks. Halfway through and at the end of the study, you’ll be asked to complete a short questionnaire on your experience participating in the study.

If you have any questions during the study, please email us stepup@example.com.

##### Study communications

1. Daily feedback when achieved goal: Great job! You had XXXX steps yesterday and achieved your goal of at least YYYY steps per day. Keep it up!
2. Daily feedback when not achieving goal: Sorry, you had XXXX steps yesterday and did not achieve your goal of at least YYYY steps. Try to stay physically active and meet your goal each day!

Game intervention
In this study, we will ask you to play a game for 12 weeks and then continue to use your device for another 12 weeks after the game has finished. The game begins on Monday.

##### Rules of the game

You begin in the bronze level and can move up to other levels: silver, gold, and platinum (the highest level). Every Monday, you will get a fresh set of 70 points (10 for each day of the week). If you achieve your step goal, then you keep your points. However, if you do not achieve your goal, you lose 10 points from your total. At the end of the week, if you have at least 50 points (achieved goal on 5 of 7 days), you advance up a level until you reach platinum. However, if you have less than 50 points, you drop down a level until you get back to bronze.

The goal of the game is to get to the highest levels (gold and platinum) and stay there as much as possible. At the end of the game, the teams in the gold and platinum levels will receive a trophy as a reward.

Please take a moment to review the rules of the game. These will be accessible on your Way to Health dashboard at any time. Remember, the game starts on Monday and lasts for 12 weeks. After the game ends, we ask that you continue to be physically active and use your device for another 12 weeks.

##### Weekly communications

1. Weekly Monday message when 50 points or greater: Congratulations! You had YY points this past week, and you are now at the XX level. You begin each week with 70 points. Keep it up! *This weekly message is sent by email (not text or voice). At the bottom of the email is a summary of the rules of the game.*
2. Weekly Monday message when less than 50 points: Sorry, you had less than 50 points this week and are now at the XX level. You begin each week with 70 points. Try to stay active and meet your daily step goal. *This weekly message is sent by email (not text or voice). At the bottom of the email is a summary of the rules of the game.*
3. Event reported (goes on the bottom of Monday email): During the past week, if you had any medical injuries or issues, visited the emergency room, or were admitted to the hospital, please contact the study team by email at STEP UP.

Summary of rules (goes on bottom of Monday email):

You begin in the bronze level and can move up to other levels: silver, gold, and platinum (the highest level). Every Monday, you will get a fresh set of 70 points (10 for each day of the week). If you achieve your step goal, then you keep your points. However, if you do not achieve your goal, you lose 10 points from your total. At the end of the week, if you have at least 50 points (achieved goal on 5 of 7 days), you advance up a level until you reach platinum. However, if you have less than 50 points, you drop down a level until you get back to bronze.

The goal of the game is to get to the highest levels (gold and platinum) and stay there as much as possible. At the end of the game, the teams in the gold and platinum levels will receive a trophy as a reward.